

What is claimed is:

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1. A composition comprising the active pharmaceutical ingredients phenylephrine and pyrilamine, the composition formed from the steps of:

- 5
- a. dissolving active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredients under conditions that will not cause decomposition of the active pharmaceutical ingredients;
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- b. mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion;
- c. transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of the active pharmaceutical ingredients;
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- d. combining substances selected from the group consisting of preservatives, suspending agents, thickening agents, coloring agents, anti-caking agents, sweetening agents, flavoring agents and pH adjusting agents to form a liquid pharmaceutical carrier; and
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- e. combining at least a portion of the second solution to the liquid pharmaceutical carrier to produce a liquid dosage form including pharmaceutically active tannate salts.

2. The composition of claim 1 wherein the active pharmaceutical ingredients are present in a range of about 0.05% to about 25.0% by weight.
3. The composition of claim 1 wherein the active pharmaceutical ingredients are selected from the group of salts consisting of maleate, citrate, chloride, bromide, acetate, and sulfate.
4. The composition of claim 1 wherein the tannic acid is natural or synthetic.
5. The composition of claim 1 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds.
6. The composition of claim 5 wherein the dispersing agent is magnesium aluminum silicate and is present in a range of about 0.05% to about 5.0% by weight.
7. The composition of claim 1 wherein the tannic acid is present in a range of about 0.05 to about 10.0% by weight.
8. The composition of claim 6 wherein the magnesium aluminum silicate and tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.

9. The composition of claim 1 wherein the tannic acid and the active pharmaceutical ingredients are present by weight in a ratio in the range of 2:1 to 10:1.
10. The composition of claim 1 wherein the thickening agent is magnesium aluminum silicate and is present in a range of about 0.5% to about 10.0% by weight.
11. The composition of claim 1 wherein the suspending agent is kaolin and is present in a range of about 0.5 to about 10.0% by weight.
12. The composition of claim 1 wherein the sweetening agents include sucrose present in a range of about 5.0% to about 50.0% by weight, and saccharin sodium present in a range of about 0.01% to about 3.0% by weight.
13. The composition of claim 1 wherein the flavoring agent is artificial grape and is present in a range of about 0.01% to about 2.0% by weight.
14. The composition of claim 1 wherein the second solvent is water and is present in a range of about 10.0 to about 75.0% by weight.
15. The composition of claim 1 wherein said second solvent is glycerin and is present in a range of about 2.5% to about 20.0% by weight.

16. The composition of claim 1 wherein the preservative is methylparaben and is present in a range of about 0.01 to about 1.0% by weight.
17. The composition of claim 1 wherein the pH adjusting agent is benzoic acid and is present in a range of about 0.05 to about 1.0% by weight.
18. The composition of claim 1 wherein the anti-caking agent is pectin and is present in the range of about 0.5 to about 10.0% by weight.
19. The composition of claim 1 wherein the pH of said liquid dosage form is in a range of about 3.5 to 6.5.
20. The composition of claim 1 wherein the pharmaceutically active tannate salts are pyrilamine tannate present at about 30mg and phenylephrine tannate present at about 12.5mg.
21. The composition of claim 19 wherein said liquid dosage form is a suspension.
22. A manufacturing process for the formation of a combination of pharmaceutically active tannate salts selected from the group consisting of phenylephrine and pyrilamine, which comprises the steps of:

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24. The process of claim 23, wherein forming a liquid pharmaceutical carrier further comprises combining preservatives, anti-caking agents, and pH adjusting agents to a fourth solvent to form a second dispersion.
- 5 25. The process of claim 24, further comprising transferring at least a portion of the second solution to the third solution to form a third dispersion.
26. The process of claim 25, further comprising transferring at least a portion of the second dispersion to the third dispersion.
27. The process of claim 22, wherein the active pharmaceutical ingredients are provided as salts or in free base form.
- 10 28. The process of claim 22 wherein dissolving the active pharmaceutical ingredients in a first solvent occurs at a temperature in range of about 20 C to 50 C.
29. The process of claim 22 wherein dissolving an active pharmaceutical ingredients in a first solvent occurs at a pH in range of about 3 to 11.
- 15 30. The process of claim 22 wherein the liquid dosage form is for immediate or sustained release of the active ingredients.

31. A composition comprising active pharmaceutical ingredients selected from the group consisting of phenylephrine and pyrilamine, the composition formed from the steps of:

- 5
- a. dissolving active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredient occurs under conditions that will not cause decomposition of the active pharmaceutical ingredients;
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- b. mixing a dispersing agent, diluent and tannic acid in a second solvent to form a first powder mixture;
- c. transferring at least a portion of the first solution to the first powder mixture, to form tannate salts of the active pharmaceutical ingredients in a second powder mixture;
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- d. adding substances selected from the group consisting of dry binding/matrix forming agents and a binder solution to the second powder mixture in order to form a granulation;
- e. combining the granulation with substances selected from the group consisting of diluent, coloring agents, sweetening agents, hardness-increasing agents, flavoring agents, and excipients; and
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- f. processing the granulation into solid dosage forms.



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32. The process of claim 31 wherein the active pharmaceutical ingredients are free bases or salts selected from the group consisting of maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate, mesylate, palmitate, and stearate.
33. The process of claim 31 wherein the tannic acid is natural or synthetic.
34. The process of claim 31 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds.
35. The process of claim 31 wherein the solvents are selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol.
36. The process of claim 31 wherein the diluent is selected from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol and is present in a concentration of about 1.0 to about 75.0%.
37. The process of claim 31 wherein the binder solution comprises material selected from the group consisting of corn starch, pregelatinized starch, potato starch, polyvinylpyrrolidone and xanthan gum and is present in a concentration of about 0.1% to about 20.0%.

38. The process of claim 37 wherein the binder solution further comprises a solvent.

39. The process of claim 38 wherein the solvent is selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol.

40. The process of claim 31 wherein the dry binding/matrix forming agents are selected from the group consisting of methylcellulose, hydroxypropyl methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl pyrrolidone and each is present at a concentration of about 0.1% to about 20.0%.

41. The process of claim 31 wherein the coloring agents are selected from the group consisting of blue, red, yellow, green, orange, and purple and each is present at a concentration of about 0.01% to about 2.0%.

42. The process of claim 31 wherein the sweetening agents are selected from the group consisting of sucrose, saccharin sodium, xylitol and sucralose and each is present at a concentration of about 0.01% to about 40.0%.

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43. The process of claim 31 wherein the flavoring agents are selected from grape, cherry, orange, lime and strawberry and is present in a concentration of about 0.01% to about 3.0%.
44. The process of claim 31 wherein the dispersing agent is magnesium aluminum silicate and is present in about 0.05% to about 15.0% by weight.
45. The process of claim 31 wherein the tannic acid is present in the range of about 0.05% to about 30.0% by weight.
46. The process of claim 44 wherein the ratio of magnesium aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.
47. The process of claim 31 wherein the tannic acid and the active pharmaceutical ingredients are present in the weight ratio 2:1 to 10:1.
48. The process of claim 31 wherein the tannate salts are pyrilamine tannate present at 30mg and phenylephrine tannate present at 25mg.

49. A manufacturing process for the formation of a combination of pharmaceutically active tannate salts selected from the group consisting of phenylephrine and pyrilamine, as therapeutic solid dosage form for human use, which comprises the steps of:

- 5 a. dissolving active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredient occurs under conditions that will not cause decomposition of the active pharmaceutical ingredients;
- 10 b. mixing a dispersing agent, diluent and tannic acid in a second solvent to form a first powder mixture;
- c. transferring at least a portion of the first solution to the first powder mixture, to form tannate salts of the active pharmaceutical ingredients in a second powder mixture;
- 15 d. adding substances selected from the group consisting of dry binding/matrix forming agents and a binder solution to the second powder mixture in order to form a granulation;
- e. combining the granulation with substances selected from the group consisting of diluent, coloring agents, sweetening agents, hardness-increasing agents, flavoring agents, and excipients; and
- 20 f. processing the granulation into solid dosage forms.

50. The process of claim 49 wherein when combining excipients with the granulation the excipients are selected from the group consisting of calcium phosphate, calcium stearate, talc, colloidal silica, magnesium stearate and stearic acid and each is present at a concentration of about 0.1% to about 10.0%.

51. The process of claim 49 wherein dissolving the active pharmaceutical ingredient in a first solvent occurs at a temperature in the range of 30°C to 50°C.

52. The process of claim 49 wherein dissolving the active pharmaceutical ingredient in a first solvent occurs at a pH in a range of 7 to 11.

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53. A composition comprising tannate salts being formed by a method comprising:
  - a. dissolving active pharmaceutical ingredients selected from the group consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredients occurs at a temperature and pH value that will not cause decomposition of the active pharmaceutical ingredients;
  - b. mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion; and
  - c. transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of the active pharmaceutical ingredients.